UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,657	12/01/2004	Hajime Yamada	P/2850-101	8759

2352 7590 03/03/2009

OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,657	YAMADA ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-4-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendment, response and IDS all filed 11/04/08 is acknowledged. Claims 3-9 have been newly added. Claims 1 and 3-9 are pending. Claim 2 stands cancelled.

Information Disclosure Statement

The information disclosure statement filed 11/04/08 has been considered.

The following rejection of record has been withdrawn, in view of the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "An external medicines for treating dermatitis: wherein a cyclodextrin including an adrenocortical steroid is dissolved in an aqueous solution containing polysaccharide; 0.025 to 0.5% by weight of the adrenocortical steroid, 0.2 to 30% by weight of the cyclodextrin, and 0.5 to 55% by weight of a dextran or pullulan are comprised; and 0.5 to 55% by weight of each xyloglucan, trehalose, laminaran, krestin, and pectin are blended; and the aqueous solution comprises at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride." It is unclear if the recitation "wherein a cyclodextrin including an adrenocortical steroid is dissolved in an aqueous solution containing polysaccharide" is different from the composition containing "0.025

to 0.5% by weight of the adrenocortical steroid, 0.2 to 30% by weight of the cyclodextrin, and 0.5 to 55% by weight of a dextran or pullulan and 0.5 to 55% by weight of each xyloglucan, trehalose, laminaran, krestin, and pectin, and at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride". It is unclear if the "polysaccharide" in line 3 is in addition to dextran or pullan or "dextran or pullan" is further defining the "polysaccharide" in line 3. The examiner suggests restructuring the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754), JP 10025240 and in further view of Schmidt et al (5,578,300).

Yamada et al teach a composition for dermatitis comprising an adrenal cortical steroid, cyclodextrin to solubilize the steroid, and water. The composition comprises 0.025-0.5% adrenal cortical steroid; 0.2-30% cyclodextrin; 0.5-55% of dextran or pullan; and an aqueous solution. The solution may further comprise glucose, mutan, lentinan, sodium chloride, and potassium chloride, and other polysaccharides. Yamada discloses all of the skin conditions that are claimed in the instant invention (see table 1) and shows that the composition is 90% effective in treating the claimed conditions.

Yamada et al do not teach xyloglucan (beta-glucan), trehalose, laminaran (beta-glucan), krestin (beta-glucan), and pectin.

Griesbach et al teach the use of water-soluble beta-glucans as therapeutic agents for skin diseases such as dermatitis, cradle cap, psoriasis, seborrhea sicca,

seborrhea oleosa, psoriasis vulgaris, ichtyoses or UV erythemas. See column 3, lines 1-10. The glucans are used in an amount of 0.1-25% and preferably 0.5-15%. See column 3, lines 10-15. Specific glucan include krestin. See table 2.

JP '240 while teaching a bath agent teach the use of saccharides such as **glucose,** fructose, sucrose, mannitol, sorbitol, maltitol, xylitol, glucuronic acid, **trehalose**, alginic acid, hyaluronic acid, ribose, arabinose and deoxyribose. Ribose, arabinose and trehalose are preferred used in an amount of 1-100%. JP '240 teaches saccharides have skin moisture retention and are particularly suitable for treatment and prevention of skin diseases including **dermatitis**. See abstract.

Schmidt teaches a method of treating dermatitis using polysaccharides especially pectin in an amount of 0.05-0.5%. See abstract and column 2, lines 50-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yamada et al, Griesbach, JP '240, and Schmidt et al and arrive at the instant invention. One would have been motivated to add beta-soluble glucans such as xyloglucan, laminaran, and krestin to Yamada's composition with a reasonable expectation of success since Greisbach teaches beta-glucans treat skin disorders such as dermatitis. One would have been motivated to also add pectin in the Yamada's composition with a reasonable expectation of success since Schmidt teaches polysaccharides such as pectin treat dermatitis and Yamada suggests the incorporation of polysaccharides in addition to dextran or pullan. Therefore, it is prima facie obvious to further include active compounds that treat dermatitis for an additive effect. Note In re Kerkohoven. "It is prima facie obvious to combine two

compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Yamada's glucose with the instant trehalose. One would have been motivated to do so with a reasonable expectation of success since Schmidt teach saccharides such as glucose and trehalose treat dermatitis. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent agent for another since the prior art establishes its functional equivalency.

With respect to the newly added claims, Yamada as well as Griesbach, JP 240 and Schmidt et al teach the compositions for treating dermatitis including the specific conditions. Accordingly, a skilled artisan would have expected to achieve the desired treatment for the claimed conditions with the composition resulting from the above combination.

Response to Arguments

Applicants' arguments dated 11-4-08 have been considered but not found persuasive. Applicants argue that that the authors of the subject reference are the same two individuals named as

co-inventors of the present application and invention. Applicants submit that the presently claimed composition, i.e., as recited in e.g., claim 1, represents an improvement over applicants' earlier work as described in the subject reference, which

improvement is neither taught nor even suggested by the disclosure contained in the reference. It is argued that the presence in the claimed composition of from 0.5 to 55% by weight of each of xyloglucan, trehalose, laminaran, krestin and pectin which are blended, components which are not taught for inclusion in the formulation described in the subject reference. However, the argument is not persuasive because the rejection is not over Yamada alone and in fact the teachings of Griesbach, JP 240 and Schmidt have been cited for other components of the claimed invention. For the argument regarding the effectiveness of instant composition (99%) in treating atopic dermatitis and psoriasis, instant claims do not recite the percentage effectiveness and further, the effectiveness of the composition not only depends on the composition but also on the patient population that is being treated for such conditions including the severity of the conditions being treated. Instant claims do not distinguish the population being treated from that of the prior art references.

Turning next to Griesbach, it is argued that the subject reference discloses a method of treating skin

conditions or skin diseases which comprises a step of applying to the skin a solution including

water soluble β-(1,3) glucans, which have intact β--(1,3) side chains that are free from repetitive

β--(1,6) linkages, as active substances. Appicants argue that the fact that the composition disclosed in the reference is lacking β-(1,6) linkages thus teaches away from the composition according to claim 1 since the xyloglucan and laminaran which are identified as required components of the presently claimed

composition do contain such a β--(1,6) linkage. Applicants'' arguments are not persuasive because while the reference prefers the absence of β-(1-6) linkages , table 2 shows that all of the glucans (with or without 1-6) linkages have activity that is significant against skin aging. Accordingly, a skilled artisan would expect significant activities with variations within glucans and accordingly employ them alone or in combination.

Turning next to a discussion of the JP '240 reference, the applicants argue that what is disclosed therein is a bath powder, that utilizes 30 to 50 g of the bath powder with 200 liters of hot water. Applicants argue that the composition recited in claim 1 is thus entirely distinguishable over the disclosure contained in the cited reference. However, the teachings of JP 240 have been cited for specific contents such as trehalose and other sugars for their effectiveness in treating the claimed conditions. A skilled artisan would have employed the components of JP 240 in the composition of Yamada to arrive at the instant invention.

Applicants argue that Schmidt U.S. '300 patent teach a method of treating allergic contact dermatitis with a formulation capable of inducing oxidative stress and a heat shock response so as to convert the allergic reaction of the allergic contact dermatitis into an irritant reaction. It is argued that the pectin component of the formulation according to Schmidt thus serves a completely different purpose from the purpose served by this material according to claim 1 of the present application. Applicants' arguments are not persuasive because instant claims do not recite any specific effect

for pectin and further, Schmidt teaches the mechanism underlying the dermatitis that is being treated with the disclosed composition

> There is provided by the present invention a method of treatment of allergic contact dermatitis, which method comprises treating a patient, typically by application to the skin, with a formulation capable of inducing oxidative stress and the heat shock response, so as to convert the allergic reaction of the allergic contact dermatitis to an irritant reaction.
>
> It is thought that the oxidative stress induces the heat shock response and converts the allergic reaction of the dermatitis to an irritant reaction, the latter having a shorter time span than the former. It is further thought that the heat shock inhibits the enzyme NADPH oxidase.

Schmidt teaches that the composition needs a hydrogen peroxide precursor to practice the method, which includes pectin (see col. 2, L 51-61).

Thus, in contrast to applicants' arguments that the closest work related to their invention is Yamada references, the other prior art also teaches various methods and compositions for treating the claimed conditions and hence the combination of the cited teachings render the instant composition as well as the method obvious.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Prior art of interest:

EP 0668072 to Kludas teaches compositions for repair and remodelling of aged and damaged skin, to restore the normal physiological interactions and functioning between various layers of skin (page 3, L 27-37 and page 4, L 23-31). The composition of Kludas comprises pectin, xyloglucan, glucan, cellulose and other plant extracellular matrix components (see page 5, L 41-44 and claim 5). In particular, Kludas teaches the composition being effective for the treatment of conditions such as dermatitis, wound healing, skin damage due to corticosteroids, etc (claim 16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611

March 2, 2009